

Exhibit 78

When is a rebate a kickback?

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Highlight: Discounts by pharmaceutical companies to middlemen are under fire

Body

By the time the Senate defeated a measure last week to reduce prescription drug costs for senior citizens, Democrats and Republicans had squabbled over everything from the cost of the Medicare benefit to the role that bureaucrats would play. But there was one point on which everyone seemed to agree: All the proposals--and most likely any legislation that eventually emerges--would have vastly expanded the power of middlemen who tout themselves as the free-market solution to containing drug costs.

Already more than 70 percent of Americans with private health insurance buy their drugs indirectly through these pharmacy benefit managers, or PBMs. Working for employers and insurance companies, PBMs provide a wide range of services, including promoting lower-cost generics and running mail order pharmacies. Most important, however, they extract rebates from pharmaceutical manufacturers in exchange for putting the manufacturers' products on their lists of approved drugs. "We generate competition," says David Halbert, chief executive of AdvancePCS, the nation's biggest PBM. "We are in the business of lowering drug costs."

Except, that is, when they aren't. PBMs are coming under increasing attack by employers, state legislatures, and a federal investigation that is fast gathering steam. Their claims are essentially the same: that manufacturers' rebates are nothing but illegal kickbacks that the PBMs use to line their own pockets instead of to reduce costs to consumers. Critics say these secret payments add up to 10 percent of the \$ 122 billion Americans spend on prescription drugs every year. "Are the PBMs driving up healthcare costs?" asks Gerry Purcell, a former PBM executive turned industry critic. "I think the answer is yes."

Favored products. The power of PBMs--the top four companies earn \$ 57 billion a year in revenue--rests in their ability to decide which drugs an employer will pay for. Just as an HMO chooses a network of preferred doctors, the PBM compiles a list of favored drugs known as a formulary. If a doctor prescribes a drug that is not on the formulary, an employer or insurance company might refuse to pay for it. If another drug is "preferred" over one that a doctor prescribes, the PBM might call the doctor and ask him to switch it. In theory, PBMs push drugs that are not only effective but also less expensive.

In practice, however, prescribing decisions are often driven not by the price of a drug but rather by how much the drug company is paying the PBM to recommend it. Critics say drug companies are paying ever bigger chunks of money to PBMs to boost sales of expensive drugs that are no better than cheaper alternatives. And while some of that money is passed on to the PBM's clients--the insurance companies or employers--much, if not most, is kept by the PBMs themselves. "The PBMs are driven by collecting rebates, not containing costs," says Chris Nee, a benefits consultant.

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Now a spate of private lawsuits seeks to force the PBMs to share that rebate money with their clients and to open their books. According to Michael Ferrara, one of the lawyers suing the industry, PBMs owe \$ 32 million to the health plan of the state of California alone.

Drug makers and PBMs guard their rebate deals jealously. But one arrangement is laid out in a lawsuit against drug giant Wyeth, the maker of Premarin, a leading estrogen therapy. Duramed Pharmaceuticals, a company that makes a cheaper estrogen product called Cenestin, contends that Wyeth signed agreements in 1999 with several PBMs, including industry leaders AdvancePCS, Express Scripts, and Caremark RX. At the same time, Wyeth raised the price of Premarin 12 percent. According to the lawsuit, Wyeth offered the PBMs broad rebates but in some cases agreed to pay only if the PBMs excluded Cenestin from their formularies. Unwilling to forgo millions in profits, says Stephen Susman, a lawyer for Duramed, the PBMs complied. In court filings, Wyeth denies the contracts were exclusive and says patients were free to buy Cenestin on their own.

In most markets, the price for an existing product falls when a new, better product is introduced. Not so with prescription drugs. Zocor, Merck's big-selling cholesterol drug, was introduced in 1991; its chief rival, Pfizer's Lipitor, was introduced in 1996. Lipitor was shown to be more effective. So what happened to the price of Zocor? From 1996 to 2001, it increased 22.2 percent. A similar situation occurred with Prilosec, the heartburn drug introduced in 1989. Its chief rival, Prevacid, was introduced in May 1995, and three similar medicines have been approved since. In response to this competition, the price of Prilosec increased 27 percent.

Perverse economics. Although the cause of these price increases is unknown, PBMs are a big part of the reason new products drive prices for existing drugs up instead of down. When a new drug comes out, the maker of the old drug often pays the PBMs more money to keep the existing drug on the formulary. The drug maker then passes on those fees to consumers in the form of higher prices. "This is a market structure based on reverse and perverse economics," says Stephen Schondelmeyer, a professor of pharmaceutical economics at the University of Minnesota. "PBMs get paid more for doing what increases drug spending."

It didn't always work this way. PBMs once earned most of their revenue from the administrative fees paid by corporate health plans. But these days, PBMs are far more reliant on drug-maker rebates. Medco, the nation's second-largest PBM, reported that it would not have been profitable for the past three years had it not been for rebates. But now that these payments have come under fire, critics say the companies have started hiding them from clients and auditors by calling them by other names. They might label them "educational grants," for instance, or "data sales fees," or "health management fees." When used legitimately, such fees are considered compensation to the PBMs for educating physicians about a drug makers' products or in exchange for prescription information about patients. (The latter practice has raised additional privacy concerns.)

Hiding the rebates also helps pharmaceutical companies maintain artificially high prices. How? By law, drug companies must give Medicaid their lowest retail price. This so-called best price must take into consideration the rebates and other incentives that manufacturers give PBMs. The more rebates a drug company has to pay, the lower the price of the drug. But if the manufacturers don't call their rebates "rebates," they don't have to factor them into their best-price calculations.

PBM executives insist that they pass along most of the rebate money to the corporate health plans, negotiating lower overall prices than corporations could get on their own. Being able to keep some of the rebate money gives PBMs an incentive to try to extract more savings from pharmaceutical companies, said Barrett Toan, the chief executive of Express Scripts. "We are part of the solution," Toan says. "Not part of the problem."

But as long as PBMs are paid to do the bidding of pharmaceutical companies, critics say they will never be able to curb rising drug costs. Purcell, the former PBM executive, cites the case of AstraZeneca and its popular heartburn medication Prilosec. AstraZeneca, Purcell says, has been paying PBMs \$ 15 to \$ 30 for every call they make to doctors urging them to switch from Prilosec to its new heartburn pill, Nexium. With 30 million Prilosec prescriptions written last year, that offer could be worth millions. Since Nexium is priced lower than Prilosec, switching may initially seem like a good deal. Yet AstraZeneca, Purcell says, is thinking much further down the road. Under state

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laws, once Prilosec becomes generic, pharmacists will automatically switch most patients to the low-cost unbranded alternative. But AstraZeneca, Purcell says, is betting that former Prilosec users, by then happily taking Nexium, will not voluntarily switch.

A spokesman for AstraZeneca declined to divulge how much the company was paying PBMs to switch patients to Nexium, saying only that Purcell's estimate was too high. Toan said Express Scripts representatives made the calls only after asking clients' permission and disclosed to the doctors that the company was getting paid. He disputed Purcell's predictions, saying that once Prilosec became generic, the company would try to switch patients off Nexium.

Accounting tricks? Although the criticism of PBMs extends industrywide, much of it stems from the controversial practices of Medco and its parent company, pharmaceutical manufacturer Merck. Last month, Merck was forced to delay its spinoff of Medco after questions were raised about whether the unit inflated its size by claiming \$ 12 billion in revenue from copayments by consumers to pharmacies--money that Medco never touched.

At the same time, several lawsuits argue that Medco pushed its clients to use more expensive drugs manufactured by Merck. Medco lawyers argue that even if the company favored more expensive drugs in some cases, it guarantees that it saves its clients money overall. Nevertheless, the Merck case has attracted the attention of Jim Sheehan, an assistant U.S. attorney for the Eastern District of Pennsylvania who has been conducting a wide-ranging inquiry into PBM practices for the past four years. Sheehan would not comment on the probe, but he is expected to lay out his case in a letter to Medco as early as this week. Sheehan is also attempting to question executives of AdvancePCS about rebates and drug switches.

Despite the growing criticism, Congress is expected to rely on the PBM model as it resumes debate on Medicare drug coverage this fall. Meanwhile, many state governments, their budgets squeezed by rising drug costs for public employees, have had enough. In June, Georgia's governor signed a law regulating PBMs. West Virginia has negotiated a deal with a PBM that would give the state a bigger share of rebates. And Vermont is leading a coalition of states that want to negotiate directly with drug makers, cutting out PBMs altogether. Says Vermont Senate President Peter Shumlin: "The days of PBMs' selling people savings while secretly lining their pockets are over."

The Drug Discount Game

[Drawing is not available.]

Drug manufacturers offer rebates to push their products.

Pharmacy Benefit Managers (PBMs) keep money critics say they should pass on to health plans.

[labels] Rebate dollars; Health plans; PBM

ILLUSTRATION BY DOUG STERN--USN&WR

Soaring drug costs

The prices of brand-name pharmaceuticals have more than doubled in a decade.

[Chart data are not available.]

[labels]1990'92'94'96'98'00

0

20

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40

\$ 60

Source: Kaiser Family Foundation; MARCELA MARTINEZ--USN&WR

Graphic

Drawing, The Drug Discount Game (ILLUSTRATION BY DOUG STERN--USN&WR); Picture, "We're not part of the problem; we're part of the solution." BARRETT TOAN, chief executive officer of the benefits firm Express Scripts. Critics say PBMs increase costs by taking manufacturers' rebates to push higher-priced drugs. (BILL STOVER--THE NEW YORK TIMES); Chart, Soaring drug costs (Kaiser Family Foundation; MARCELA MARTINEZ--USN&WR)

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